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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,750	03/20/2002	Nobuhiko Nakashima	3190-015	8810
33432	7590	11/16/2004	EXAMINER	
KILYK & BOWERSOX, P.L.L.C. 53 A EAST LEE STREET WARRENTON, VA 20186			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 11/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/088,750	<b>Applicant(s)</b> NAKASHIMA ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' supplemental response to restriction requirement and amendment filed September 2, 2004 is acknowledged. In the amendment, claims 5-7 have been amended, and new claims 20-29 have been added, thus, claims 1-29 are pending. Upon reconsideration, a new restriction to claims 1-29 is made as follows:

#### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, 9-15, 18-25, 28 and 29, in part, drawn to an RNA higher-order structure having a function for promoting a translation activity which comprises a base sequence containing SEQ ID NO:1-6 or 7, or a related sequence; a recombinant vector containing a polynucleotide comprising at least one base sequence; a transformant that has been transformed with the recombinant vector; a method for synthesizing a heterologous protein utilizing a polynucleotide comprising at least one base sequence; a method for synthesizing a heterologous protein utilizing a recombinant vector containing a polynucleotide comprising at least one base sequence; a method for synthesizing a heterologous protein utilizing a transformant which is transformed with a recombinant vector containing a polynucleotide comprising at least one base sequence; or a method for initiating synthesis of arbitrary heterologous protein using a polynucleotide comprising a base sequence; or, a method for synthesizing a heterologous protein

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utilizing a polynucleotide encoding the heterologous protein and a polynucleotide that promotes translation activity and has an RNA higher-order structure; where the protein synthesis is carried out in a cell.

II. Claims 5-11, 13, 15-17 and 20-27, in part, a method for synthesizing a heterologous protein utilizing a polynucleotide comprising at least one base sequence having an RNA higher-order structure; a method for synthesizing a heterologous protein utilizing a recombinant vector containing a polynucleotide comprising at least one base sequence having an RNA higher-order structure; a method for initiating synthesis of arbitrary heterologous protein using a polynucleotide comprising a base sequence having an RNA higher-order structure; a method for synthesizing a heterologous protein utilizing a polynucleotide encoding the heterologous protein and a polynucleotide that promotes translation activity and has an RNA higher-order structure; where the protein synthesis is carried out in a cell-free system.

Should Group I or II be elected, applicant is required to select one nucleotide sequence from SEQ ID NO:1-7. Any nucleotide sequence, absent factual data to the contrary, is a distinct polynucleotide. This is not a species election.

The claims of Groups I and II are directed to different inventions which are not linked to form a single general concept. The methods of Groups I and II are distinct from each other because they have different method steps and utilize different materials, for example, the method of protein synthesis of Group I is carried out by transforming the cell with a recombinant vector in a host cell, while the method of for protein synthesis of Group II is performed in a cell-free system, e.g., using a wheat germ extract. Furthermore, the claims containing different sequences do not have in common the same or corresponding technical features. In particular, each

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nucleotide sequence is directed to a distinct sequence containing a RNA higher order structure. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

A handwritten signature in black ink, appearing to be 'Chih-Min Kam', with a long horizontal stroke extending to the right.

CMK  
November 13, 2004